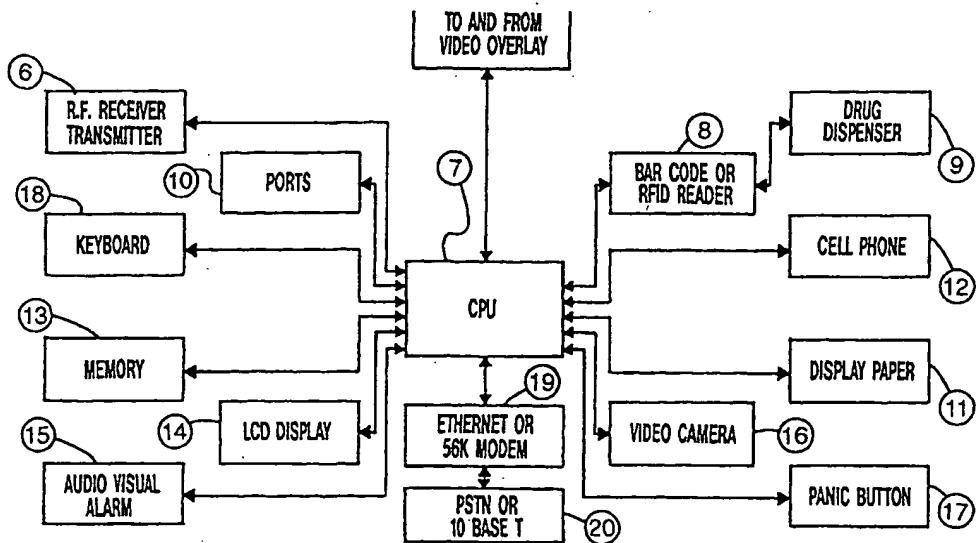




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(54) Title: INTERACTIVE PRESCRIPTION COMPLIANCE AND LIFE SAFETY SYSTEM



(57) Abstract

An interactive prescription compliance and life safety system provides remote and on site verification of procedures related to the health status of a person, including taking of medicines (8, 9), responsiveness to queries (11, 12), and attendance of health care and service providers (18) in the home by providing for signals to and from a person's location (19, 20), with alarm activation (15) when a deviation from a preprogrammed procedure occurs.

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INTERACTIVE PRESCRIPTION COMPLIANCE
AND LIFE SAFETY SYSTEM

This invention relates to correctly taking of Prescription Drugs through an interactive compliance system, which incorporates third party monitoring and interactive participation by the user of said drugs. Medical monitoring and personal safety and life safety are additional benefits to this invention.

Prior Art

While prescription drugs are modern miracles in preserving and extending a person's life, not taking prescriptions as required (non-compliance) has become a major health problem. Additionally people living alone, particularly the elderly, are subject to other incidents such as falls and drug reactions rendering them unable to call for help.

Non-compliance in prescription drug taking is putting an enormous strain on the entire health care system today. Estimates of cost to the United States economy range from 50 to as high as 100 billion dollars per year. It is estimated that 17 percent of all Emergency room visits are the direct result of a prescription drug misadventure (non-compliance). Other results of non-compliance include hospital and nursing home admissions as well as lost wages and lower productivity.

As the population ages, compliance becomes a source for even more concern. Population experts say by the year 2003, 83 million Americans will be over the age of 50, and by the year 2010, that figure will be over 100 million. Currently no system exists to assure compliance in the taking of prescription drugs. Pager systems such as United States Patent 5,623,242 to Dawson/Byron April 22, 1997; provides that a signal is sent from a central data base containing all the pertinent information of the prescription to an individual pager reminding them to take the medication. However, such a system does not insure the medication

has been taken. To ensure compliance, an interactive response should be sent back to the central database by the individual taking that specific medication. While drug compliance will go up using the pager system, 5 patient response to the pager signal, or other alarm type signals, ensure an even higher compliance rate.

In-home safety and security is a growing concern for all people not just Americans. Safety and security companies have traditionally provided companies and 10 wealthy individuals with services such as CCTV (closed circuit television), fire and burglar alarm monitoring and recently interactive video. Currently systems specifically for the home (wired or wireless) are now available. These services include smoke, fire, burglar, 15 water, temperature, keyless door entry and carbon monoxide detection. Research in this area show specific patents but no central controller patent. United States Patent 5,673,016 to Lutes September 30, 1997, describes a visitor information system. While the communication 20 links are available between the home or institution and safety/security companies, "an Interactive Prescription Compliance System" is not offered. Wireless alarm systems for compliance safety and security simply are not in the United States Patent database. United States Patent 5,625,338 to Pildner April 29, 1997, is a wireless keypad to control communications to a control panel for entrance and exit control. United States Patent 5,598,427 to Arthur, January 28, 1997, appears to be a burglar alarm system.

30 Continuing with in-home systems; pill or medication dispensers form home use such as United States Patent 5,405,011 to Haber April 11, 1995, United States Patent 5,575,392 to Cutler November 1996, and United States Patent 5,641,091 to Danes/Havar June 24, 1997, do not 35 incorporate the latest technologies such as bar codes or RFID tags, but rather are mechanical in nature. United States Patent 5,609,268 to Shaw March 11, 1997, is a microprocessor controlled pill dispenser, but it too

fails to incorporate interactivity with the user and does not use other interactive components such as bar code and RFID technology. Drug compliance can now be assured with such dispensers.

5 Bar codes and RFID tags are by their very nature wireless interactive or active devices. Bar code readers and RFID tag readers by design could be wired to a fixed point or wireless. U. S. Patent 5,640,002 Ruppert June 17, 1997 is a portable (wireless) RFID tag and bar code reader for grocery stores. United States Patent 5,646,592 to Tuttle July 8, 1997, is a RFID tag for security of containers such as suitcases. United States Patent, 5,602,380 to Bishop February 11, 1997, is a line of sight bar code scanner/reader using infrared technology. United States Patent 5,721,421 to Van Doukeluur February 24, 1998, is a wireless bar code reader used for identifying shelf tags. The required information is then transmitted to a terminal processed and then retransmitted to an RF to a base station. All 10 these systems have the following features in common: (1) merely state of the art technology, (2) not a consumer product and interactive prescription compliance device. Therefor, drug compliance is not an obvious benefit of these systems.

25 U.s. Patent 5,700,998 to Palti December 23, 1997, uses bar code technology. A bar code is printed on pills and a bar code assigned to a patient. If the patient's bar code does not match the pill bar code, an alarm is generated indicating a mismatch of patient and medication. This system appears to be institutional in nature, as does United States Patent, 5,713,487 to Coughlin February 3, 1998, an automated medication system using bar codes and manipulating arms. U. S. Patent 5,564,803 to McDonald October 10, 1996, is a 30 portable nursing center utilizing bar codes and a keyboard data entry system to open specific drawers containing medications. While these systems seem to 35 ensure some form of compliance, none provide for

personal safety and security.

Cable Set Top Boxes are becoming commonplace in homes, assisted living centers, retirement centers, nursing homes, hotels and adult day care centers. 5 United States Patent 5,512,935 to Majeti April 30, 1996, appears to be a cable set top box which flashes messages to individuals on personal computers. United States Patent, 5,649,283 to Goller July 15, 1997, is a device used to ensure the correct programming is being received 10 at the television set of a consumer. United States Patent, 5,631,903 to Dianda May 20, 1997, is a cable set top box which controls television sets. U. S. Patent 5,727,052 to Sizer March 10, 1998, is a system to record and display information at a remote location using that 15 location's recording unit over a telephone network. Cable set top boxes today do not have the capabilities of receiving wireless data from sensors placed in the home or institutional settings. They also do not have bar code or RFID readers or telephone jacks to reach a 20 customer service center via the PSTN or the cellular network. Until now there has not been a need for such features.

If a means were developed to remind patients to take medication correctly or at prescribed intervals 25 whether at home or away, plus add the feature of assuring compliance through interactive response, emergency room visits, hospital or nursing home admissions would be greatly reduced. Couple the drug compliance feature with medical monitoring such as, but 30 not limited to, electrocardiogram, oxygen and renal, plus in home or room safety and security. Medicare, Medicaid, third party insurance and personal financial costs would be reduced dramatically. An additional Benefit would be the monitoring time spent by visiting 35 nurses through electronic time cards. The visiting nurse enters in a PIN code identification number upon arrival and repeats the procedure upon departure, thus verifying and recording time spent with a patient,

eliminating a major source of Medicare fraud. Other service providers, such as therapists, oxygen delivery person or Meals-On_Wheels people, could also be assigned a PIN code identification number. All of the data would 5 be stored int he Customer Service Center and available to the care givers, government programs (Medicare/Medicaid) doctors and insurance companies for each patient.

My Interactive Prescription Compliance System uses 10 a PSTN, bar code readers, wireless monitoring devices and a cable set top box like console. By PSTN is meant phone system telephone network. Provisions in the console have incorporated, through interconnections and stuffing options, to add automated prescription 15 dispensers, cellular phone lines, cable and broadcast Tv inputs and pager or palm pilot-like devices.

Functionality of all of these features described 20 have been developed in theory and through custom electronics work in my Interactive Prescription Compliance System. Presently the research of existing 25 systems reveals no clear complete and total embodiment of the proposed patent I have submitted. The cost for the care of terminally ill patients such as AIDS and cancer patients, plus the growing aged population, would become substantially less with the use of my Interactive Prescription Compliance System. Use of this system would reduce the chance of non-compliance by over medication.

ADVANTAGES OF INTERACTIVE PRESCRIPTION

30 COMPLIANCE SYSTEM PATENT

- A. Prescription drug compliance increased
- B. Utilizes new technology combined with existing devices
 - 1. ASIC Semiconductors (application specific integrated circuit)
 - 2. Bar code scanners and readers
 - 3. RFID tag scanners and readers
 - 4. Bar code labeled or RFID tagged

prescription vials or microprocessor controlled prescription dispensers labeled or tagged with same

5 5. Use of 433MHZ and 900MHZ band for home sensor and cordless phone

6. Use of 125KHZ, 13.%^MHZ and 2.45GHZ band for RFID tags.

C. Interactive response required by patient to central station

10 1. No response to reminder -- patient is called

2. Still no response caregiver is dispatched to site

D. Personal safety and security

15 1. Fire, burglary, water, temperature, electricity, carbon monoxide alarms, panic buttons (Help Me I've Fallen Down), perimeter monitoring (Alzheimer patient) keyless entry systems, interactive video/audio

20 E. Visiting nurse and other caregiver monitoring (Meals-On-Wheels, therapists, etc.)

F. Medical monitoring electrocardiogram, renal, oxygen, etc.

25 G. Individual patient monitoring through Interactive Video

H. Central Station monitoring and database storage of compliance on noncompliance

I. Reports of all activities available to all interested parties

30 INTERACTIVE PRESCRIPTION COMPLIANCE

AND LIFE SAFETY SYSTEM DRAWINGS

Figure 1: Rendering of Interactive Prescription Compliance System Drug Dispenser;

Figure 2, Figure 5 and Figure 6:

35 Flowchart of Interactive Prescription Compliance System Box showing Prescription Dispenser utilizing bar code or RFID tag technology also shown optional Palm Pilot or Beeper-like device, optional video

camera, optional cellular phone, wireless life safety devices and wireless panic buttons;

5 Figure 3: Home Interactive Prescription Compliance System Architecture with Compliance Set Top Box and Interactive Audio Visual option;

Figure 4: Institutional Interactive Prescription Compliance System Architecture with Compliance Set Top Box and Interactive Audio Visual option;

10 Figure 7: Prescription vial, being either bar coded or RFID tagged.

Description of Figure 1 -- Interactive Prescription Compliance System Drug Dispenser.

15 Referring to Figure 1, major components consist of housing 110 which conforms to all applicable standards for UL 2034 specifications. Bar code or RFID tag 1.11 affixed to housing by means of printed bar code label or preprogrammed RFID tag. Information contained in bar code or RFID tag 1.11 will be used to activate some, but 20 not all command controls in the Customer Service Center (Figure 3 and Figure 4 to Interactive Prescription Compliance System Set Top Box Figure 2.) Custom electronics 1.12 are microprocessor based utilizing standard cell and ASIC designs and receiver input from 25 compliance set to box (Figure 2) by means of a communications link present via a connector which is part of the Interactive Prescription Compliance Dispenser Stand 1.15 which affixed to Interactive Prescription Compliance Set Top Box Figure 2. Custom 30 electronics microprocessor based 1.12 processes data received from Customer Service Center, Figure 3 and Figure 4, and activates miniature stepper motor and spindle 1.13. A prepackaged single dose serrated medication packet spooled containing at least a one week 35 supply of meds 1.14 is then dispensed at correct intervals, one packet at a time from data supplied from custom electronics 1.12 and rotated out of dispenser by motor spindle 1.13. In the case of multiple

prescription drugs prepackaged spool of meds 1.14 will be packaged according to prescription directions provided by patients doctor and filled at mail order facility, Figure 3 and 4. Each individual prepackaged 5 medication packet shall be of cellophane-like material and have printed on it patient name, drug name, doctor's name, other information could be added as required. An extension cord- like cable of sufficient length could be affixed to the dispenser allowing a bedside or chair 10 side use of said dispenser. It is possible to completely control this dispenser by the Customer Service Center. This is accomplished by control signals sent by the Customer Service Center dispensing packets or "locking" the dispenser. The dispenser is CPU based 15 with flash memory, which allows complete control.

Description of Figure 2 -- Interactive Prescription Compliance Console.

Referring to Figure 2, the completely Interactive Prescription Compliance Console is a microprocessor 20 based system which utilizes cable set top box technology plus unique features relating to compliance and safety for the individual user.

Figure 2 illustrates in block diagram form the theory of operation beginning with normal broadcast 25 cable television signals (2.1) received by the users' Compliance Console and in the case of a cable signal are then processed by the channel 3 demodulator 2.2 or in the case of a broadcast signal, Section 2.2 is designed with circuitry to directly pass signal to the user's 30 television set. Continuing with Figure 2, the cable signal is demodulated then digitized and synchronized (2.3) and passed to the channel 3 modulator (2.5). The cable signal is then modulated (2.5) and sent to user's television. Channel selection is accomplished by use of 35 standard wireless infrared emitter/detection circuit (remote or clicker). The cable broadcast signal could be completely independent of the systems CPU (2.7) and the video overlay circuit (2.4).

More particularly, an appropriate group of parts for carrying out the functions of this invention are as follows:

SET TOP BOX STANDARD FEATURES

- 5 1. CPU
2. Solid state memory
3. RF (radio frequency) Receiver
4. ports including RS232, RJ11, RJ45, PCMCIA, VGA, Smart card
- 10 5. user interface with alarm and reset buttons, for example PS/2 Type Key board
6. Display (liquid crystal or other readout)
7. Video Overlay Circuit
8. Audio or Visual Alarm
- 15 9. Bar Code or Radio Frequency Identification Tag (RFID) Reader or Scanner
10. Drug Dispenser Port
11. Modem (preferably 56 K or better)
12. Ethernet 10 Base T Converter or WAN equivalent
- 20 13. Auto Dialer
14. Stand-by Battery Power 24 Hr. Min.
15. Priority Interrupt

SET TOP BOX OPTIONAL FEATURES

1. Wireless Safety and Security Devices
 - 25 a. Fire Alarm
 - b. Burglar Alarm or Motion Detector
 - c. Temperature Sensor
 - d. Carbon Monoxide Detector
 - e. Water Sensor
 - 30 f. Electricity Sensor
 - g. Panic Buttons, for example wireless personal safety wrist or pendant button
 - h. Perimeter Limiting Alarm (Alzheimer Patient Wandering Off)
 - 35 i. Video Camera
 - j. Keyless Door Entry
2. Display Pager
3. Cellular Telephone or wireless telephone

4. Drug Dispenser
5. Interactive Audio or Video medical monitors, including but not limited to, electro cardiogram, renal function, oxygen and blood pressure.

5 The System (Figure 2) will contain DRAM and FLASH Memory (2.13) sufficient enough to allow for the operation of all options: RF Receiver/wireless monitors (2.6), Display Pager (2.11), Cellular Phone w/Display (2.12), Interactive Video (2.16) and Panic Button (2.17). The Flash Memory section of the system (2.13) 10 also allows the Customer Service Center (Figure 3, Section 314 and Figure 4, Section 414) to communicate new prescription information and also to allow control 15 by the Service Center to turn on/turn off or reprogram other features of the system, including the ability to lock the Prescription Dispenser System (Figure 1).

20 The Interactive Prescription Compliance Console has been designed with multiple unique features to assure maximum prescription drug compliance and safety. The CPU 2.7 has been programmed with a unique address (PIN code) also configured to accept packetized data through circuitry designed in section 2.20 which interfaces with the PSTN or a 10 BASE T system. The 10 BASE T system is 25 part of the Ethernet system. A bar code/RFID tag reader (2.8) has been incorporated with the interactive system. It is required to correctly identify the user and the user's bar code or RFID tag of the prescription vial, Figure 7, and/or also to identify the user and the users 30 bar code or RFID Tag of Drug dispenser (2.9). The Drug Dispenser is connected to the Interactive Prescription Compliance System through a cable and RS232 port like connection which is present on both the Set Top Box (Figure 2) and Drug Dispenser and stand (Figure 1).

35 Interactive Compliance could be accomplished by user removing serrated package of medication breaking the infrared emitter detector circuit dispenser 1.16. The meds are automatically dispensed per SIG (dosage and

intervals) recommended by the doctor and programmed in the Customer Service Center. That circuit interruption generated a signal to dispenser custom electronics (1.12) to Interactive Compliance Reminder System Set Top Box CPU 2.7 (Figure 2) to Customer Service Center, which stores in its database that the meds package has been removed and compliance has occurred.

Another Interactive Compliance method would be to pass the pill vial (Figure 7) in front of the bar code/RFID tag reader after alarm reminder signal has been set by Customer Service Center to users, the Interactive Prescription Compliance Console reminding user to take medication. Such action taken by user (bar code/RFID Swipe) generates a signal to CPU (2.7) back to Customer Service Center identifying which prescription medication user is about to ingest. If the bar code RFID tag information on Medication Pill Vial (Figure 7) does not match medication information at Customer Service Center, user is immediately notified by telephone or other means. If information supplied matched, Customer Service Center records the Compliance event in its database. An extension core like cable could be affixed to reader allowing for bedside or chair side use.

If the user does not respond to the alarm reminder signal after two (2) attempts by the Customer Service Center, the primary caregiver would be notified. This action would ensure the user would be in compliance. Dates, times of non-compliance, as well as caregiver notification are recorded in the Customer Service Center data base.

The keyboard of the System (2.18) will be conventional cable set top box PS2 type and be accessorized with alarm buttons having priority interrupt on the users telephone line and direct dial capabilities to the fire and police departments (911), Customer Service Center and to the designated caregiver. An optional compliance button could also be added which

would be depressed by the user. It would be depressed only after the user had swiped the prescription vial past the bar code (RFID) tag reader and matched the data present in the Customer Service Center. Pressing the 5 compliance button would generate a signal back to the Customer Service Center that complete compliance had occurred. These buttons will be marked in accordance with symbols complying with the Americans with Disabilities Act. Additional auxiliary buttons, will be 10 able to be programmed by the user to call other entities on a priority basis such as a doctor or next-door neighbor. The keyboard will be physically enlarged and back light to allow for easier use by the sight impaired or the physically handicapped. The keyboard (2.18) 15 would also be the means of having visiting nurse, therapist, caregiver, meals on wheels or medical equipment provider record when these services and goods were provided. An identification number (PIN code) would be assigned to these individuals. Log-in and log- 20 out entries would be required of these service providers to alert the Customer Service Center of the Dates and Times service and goods were provided to user. Failure to log-in or log-out by these individuals would result in an alarm condition at the Customer Service Center and 25 notification of same would be conveyed to the users' primary caregiver.

The color liquid crystal display (2.14) will be of sufficient size and back light allowing the user of average or slightly has than average eye sight to see 30 the Interactive Compliance Reminder Message. "Mrs. Jones 3 PM Tuesday, March 17 take your blood pressure medication." Other information could be displayed showing the user the size shape and color of the medication to be taken or special instructions like -- 35 "take with meal" "take with mild". this display could also be an unlit black and white LCD.

Audio visual alarms (2.15) are also a permanent feature of the Interactive Prescription compliance

System. As the drug compliance message is generated from the Customer Service Center and transmitted to the users Set Top Box LCD Displays and additional sub-carrier signal activating the audio/visual alarm. It 5 consists of a piezoelectric like speaker with an audio output level of approximately 85DB and a flashing LED. the audio alarm and flashing LED will alert user that a predetermined time has elapsed and the user is required to take more medication. This alarm unit will continue 10 intermittently beeping and flashing for a period of three minutes or until the compliance button has been pressed. Failure to press the compliance button within three minutes results in a system reset and the Compliance signal is retransmitted from the Customer 15 Service Center and the three minute alarm is again sent to the user. Failure for a second time to respond by the user within three minutes, generates an alarm condition at the Customer Service Center. A telephone call is then placed by the Customer Service Center to 20 the user. Failure by the user to respond results in the Customer Service Center contacting the authorities to check condition of user. This audio/visual alarm could be wired with an extension cord-like cable of sufficient length to allow it to be placed next to a 25 bed, chair or central location. This alarm could also be wireless.

The Video Overlay Section (2.4) of the Interactive Prescription Compliance System allows compliance reminder special instructions and even advertising to be 30 scrolled across the bottom of the users television set. This messaging would not disturb the current programming but would rather be like a weather service "Severe Thunderstorm Warning" generated by the Customer Service Center. "Mrs. Jones, it is time to take your blood 35 pressure medication, please remove your medication from the dispenser." Or without a dispenser -- "Mrs. Jones, it is time to take your blood pressure medication, please pass the prescription vial in front of the bar

code/RFID Tag Reader."

The system will also be equipped with an RF Receiver, usually either 433MHZ or 900MHZ (2.6). This receiver will allow the user to add wireless sensors such as smoke, carbon monoxide, temperature, electricity, burglar alarm, keyless door entry, wireless perimeter alarm (a device to notify Customer Service Center or caregiver that the user has gone beyond prescribed boundaries) and panic buttons (Help I've Fallen Down) (2.17). Connection to the Customer Service Center of these sensors will be accomplished through an automatic dialer activated by the sensors or panic button generating a priority dial and alarm signal. All of these alarms sensors are currently available on the open market and the RFID receiver has been designed with custom ASIC devices to accept the sensors output. Other wireless sensors will be added but not limited to oxygen, electrocardiogram, renal and blood pressure.

Input of data to the Interactive Prescription Compliance System will be accomplished through use of RS232 type ports, RJ11 style telephone connectors and PCMCIA slots (2.10). Other input devices are an Ethernet adapter or 56k Modem (2.19). These built in interconnects allow the System to communicate to the Customer Service Center or other sites through the PSTN, Cable, Ethernet (Lan & Wans) or the optional cellular phone connection (2.12).

An interactive audio/Video camera system connection (2.16) may optionally be installed on the Interactive Prescription Compliance System Set Top Box. This connection will be accomplished through custom logic and an RS232 type multifunction cable/connector, thus allowing the Customer Service Center and other individuals to view the user via the PSTN or Internet. Other viewing options can be accommodated such as a hard wired system.

Referring to Figure 7, the Display Pager-like device allows the user freedom to move away from the

user's home or room. The user or Caregiver notifies the Customer Service Center of plans to be Physically away from the Interactive Prescription Compliance System for an extended period of time. This notification can be 5 accomplish via the conventional PSTN or optimal cell phone. If the user has a system using a dispenser, Figure 1, the Customer Service Center then transmits the data stored in the Center for the user causing the dispenser, Figure 1, to dispense the medication 10 necessary for the period of time user will be away from the primary system. The pager-like device would be on line with the Customer Service Center and the Interactive Prescription Compliance System. Both the System and pager-like device would have the same 15 telephone number. The pager-like device would be equipped with reprogrammable memory and battery operated. This feature allows the Customer Service Center, with prior user notification, to download the SIG) dosage and interval information) and alarm data and 20 time to this pager-like device. This would allow the user to take the device and medication away from the home or room. The user would be notified by audio beeper-like signal or vibration and a text message displayed on the pager. Downloading of data and battery 25 charging of the pager to the Interactive Prescription Compliance System would be accomplished by a standard connection, such as an RS232 port connecting the pager stand and the System. The pager stand would contain a battery charger, which would be connected by a line cord 30 to a conventional AC consumer outlet.

Referring to Figure 6, the cellular telephone has a dual function. The cellular telephone could be primary voice and data links to the Interactive Prescription Compliance System. This would thereby 35 eliminate the hard wired connection to the Customer Service Center and the PSTN. An additional function is off premise notification to the user of the SIG (dosage intervals). compliance of prescription drug taking

would occur by contacting the Customer Service Center to dispense the correct amount of packetized medication from the Interactive Prescription Compliance Drug dispenser (Figure 1). The user would then physically 5 take the medications dispensed and the Customer Service Center would simply call the user's cellular phone and advise same which medication to take at the correct time.

Economics of scale require the Interactive 10 Prescription Compliance System to be manufactured using multilayered and socketed Mother/Daughter Board techniques, using this procedure allows levels of service for the options available to the basic system. The basic system specifications and staffing for level 15 of service options are defined.

**HOME INTERACTIVE PRESCRIPTION COMPLIANCE
AND LIFE SAFETY SYSTEM**

Referring to Figure 3 and Figure 4, the patient's doctor writes prescription containing the following 20 information: patient's name, doctor's name, drug name indicating whether or not generic replacement is acceptable, drug strength, drug quantity, SIG (dosage intervals) and amount paid. The pharmacist requires the following in addition to information provided on 25 prescription form: patient's address, patient telephone number, date of birth and sex. The pharmacist creates the following information: Rx number, refill number, date and time sold. All of this information is entered into the pharmacy data entry workstation. This 30 workstation is networked to the bar code label printer using an RS232 port and creates the label and unique bar code for the patient. The entire patient prescription data packet is sent to the pharmacy data processing center 3.3 and 4.3 and is compared to other 35 prescriptions the patient may also be taking or has on file. If there are other prescriptions present in the data processing center, data base 3.3 and 4.3, for the same patient, drug interactions are possible because

some patients have multiple doctors. If a drug interaction is found, the data processing center 3.3 and 4.3 then the established communication link satellite, PSTN, Lan or WAN, notifies filling pharmacist. This is 5 an added precaution. If there are no drug interactions, the pharmacy system creates prescription label including a patient specific bar code. The new technology of RFID tags are created using the same procedure. Obviously the label is created by the read/write RFID tag is 10 programmed by the RFID tag programmer present in the prescription filling pharmacy, 3.1, 3.2, 4.1 and 4.2. the prescription is then filled the label/bar code or label RFID tag are affixed to the vial, Figure 7. The bar code or RFID tag will contain, but not be limited 15 to, the patient's name and unique prescription number. Other patient information will be stored in the filling pharmacy data base.

The mail order pharmacy, 3.2 and 4.2, fills 20 prescriptions using the identical procedures of the retail pharmacy. Two additional functions are performed at this site. First the filling of the dispense with packetized medication is completed, including application of pharmacy bar coded label on RFID tag. Second, the mail order facility does exactly as 25 prescribed; delivers the pill vial or interactive drug dispense to the patient's extended care address or home.

Nightly procedures for both the retail pharmacy and the mail order pharmacy is to download the prescription data from the pharmacy data entry work station to the 30 store or mail order pharmacy server (3.1, 4.1, 3.2, 4.3). this data is then data compressed, packetized and transmitted to the data processing center (3.3 and 4.3) frame relay, PSTN, POTS, LAN, WAN, and Satellite transmission lines could be used. The download to the 35 data processing center occurs at off peak hours usually 2 am Central Standard time.

Continuing with Figure 3 and Figure 4, the data processing center is the central location of all

patient, doctor, prescription, insurance, bar code or RFID tag data. This allows the modern pharmacy chain store and mail order facilities to secure nationwide and soon worldwide central data storage, thus service as the 5 pharmacy drug information source for the Customer Service Center (3.4 and 4.4). the interactive communication link between the data processing center (3.3 and 4.3) and the Customer Service Center should be a dedicated T2 type or better, or satellite connection.

10 The data processing center (3.3 and 4.3) download all patient doctor prescription insurance, bar code or RFID tag information to the Customer Service Center (3.4 and 4.4 on a daily basis. The following is then received from the data processing center:

15 1. Patient's name, address, phone number, sex, data of birth

2. Doctor's name, address, phone number, other doctors' prescriptions

3. Prescription number

20 4. Bar code/RFID tag code

5. Number of refills

6. Drug type (generic ok)

7. Quantity

8. Date and time sold

25 9. Interactive Compliance Reminder Set Top Box

10. Pager serial number

11. Accessory list

30 a. Wireless alarms

b. Interactive audio visual

c. Cellular phone number

d. Pager serial number

e. Interactive Compliance Reminder Prescription Dispenser serial number (Figure 1)

35 f. Billing method (credit card, check or cash)

g. Insurance company information

h. Medicare/Medicaid

Continuing with Figure 3 and Figure 4, the Customer Service Center receives the patient pharmacist information and stores the data. The Customer Service Center contacts the user via PSTN lines or other communications links, and obtains the following information:

1. Patient's name, age, sex, prescription number
2. Doctor's name, address, telephone number
3. SIG, dosage amount and time of day
- 10 4. Number of refills
5. Drug type
6. Quantity
7. Date and time prescription bought or received
8. Interactive Prescription Compliance Set Top
- 15 Box serial number
9. Primary care giver name, address and phone number
10. Call list of other care givers
11. Accessory list
 - 20 a. Wireless alarms
 - b. Interactive audio visual
 - c. Cellular phone number
 - d. Pager serial number
 - e. Interactive Prescription Compliance Dispenser serial number
 - 25 f. Billing method (credit card, check or cash)
 - g. Insurance company
 - h. Medicare/Medicaid
- 30 After Customer Service Center conducts live interview with patient or caregiver, the data collected is entered in the main frame data bank and compared to the pharmacy data for errors. If none are found, the Initialization Procedure for the Interaction System begins.
- 35

INITIALIZATION:

1. Determine user phone tone or pulse (dial 9)
2. PIN number assigned System Set Top box

3. PIN number assigned to Drug Dispenser
(optional)

4. Level of service

5 a. Turn on wireless alarms, Interactive
Audio/Video Pager, other monitoring
devices (oxygen, rental,
electrocardiogram)

5. PIN number other service provides

10 a. Visiting nurse, meals on wheels, medical
equipment suppliers. (This feature is
extremely effective in eliminating
Medicare/Medicaid fraud by requiring
other service providers to log-in and
log-out to identify service or goods
provided. This is accomplished through
15 the keyboard or bar code/RFID tag reader
on the Interactive Compliance Reminder
Set Top Box.)

6. System test

20 The Customer Service Center will license from
Medispan or First Data or other sources, the
pharmacological information such pill size, shape,
color, drug interaction/reaction and special ingestion
instructions. This information will be sent to the user
25 and displayed concurrently with the Compliance Alarm
Message Signal. This information is identical to
information contained in pharmacy providing the
prescription.

Description of Figures 3 and 4 -- Home Interactive
30 Prescription compliance System Architecture with
Compliance Console and Interactive Audio Visual Option
and the Institutional Interactive Prescription
Compliance System Architecture with Compliance Set Top
Box and Interactive Audio Visual option.

35 Referring to Figure 3 and 4, after initialization
is completed, the Interactive Prescription Compliance
Set Top Box functions in an identical manner, whether in
the users' home, assisted living center or retirement

community. The initialized version of Figure 4 may use a LAN or WAN.

More particularly, a flowchart of personal information required and data storage location can be set out in chart form. A suggested chart form is as follows:

	<u>Customer Service Center</u>	<u>Data Processing Center</u>
	Data Processing Center data received	Doctor Name, address, phone number Patient Name, address, phone number
10	Telephone interview w/patient to recheck data processing center info, date/time prescription received, installation of system, Set Top Box pin number, number of primary caregiver, name, address, phone Emergency phone numbers service providers pin numbers, police, fire, hospital, etc.	. Drug Name/quantity (generic) . SIG dosage & intervals . Number of refills . Prescription number . Date and time sold . Dispenser bar code/RFID tag . Bar code or RFID tag code . Drug interaction/reaction check . Serial number Set Top Box
15	Initialized Set Top Box and options phone	. Options, wireless alarm, medical monitors, pager number, wireless
20	System check	number
	Software updates	. Supplier advertising
	Options added/deleted	. Pharmacological data
25	Medispan/First New drug regimens	Data
	Source of all exception reports	. Billing method (credit card, lease
	Compliance - Insurance - Alarm - and Service Providers	check, cash, Medicare, Medicaid)
30	Level service letter sent to patient - caregiver	
	<u>Patient Room, Apt. or House Order</u>	<u>Pharmacy Retail or Mail</u>
35	System installed	. Doctor name, address, phone number
	Telephone interview with customer number	. Patient name, address, phone
	service center - level of service checked	date of birth, sex . Drug name, quantity, generic,
40	SIG	
	Patient - caregiver verifies all information	dosage and intervals . Number of refills
	Method of payment	. Prescription number
	Patient participates in system	. Refill number
45	check, bar code swipe--RFID swipe	. Date, time sold
	Interactive Compliance Reminder	. Bar Code or RFID Tag code

System fully functional
5
phone number
10
lease,
Drug interaction/reaction check
Mail order (load medicines in
optional dispenser or fill bar
coded or RFID tag
prescriptions)
Options, wireless alarms, medical
monitors, pager number, cell
Billing method (credit card,
check, cash, Medicare/Medicaid)

Referring to Figure 5, this is a block diagram of the information collected by the pharmacy data processing center and Customer Service Center. Figure 5 also shows where the collected data resides in each facility. This graphically depicts how interactive and redundant the system is, thus assuring correct medication. Options such as wireless alarm, service provider PIN numbers also redundantly checked, as depicted here in Figure 5. Any changes in drug regimen are downloaded from the Customer Service Center to the user's Interactive Prescription Compliance System. These changes are accomplished utilizing the PSTN and the user's system reprogramable memory, preferably with redundant data at the customer's site.

Description of Figure 7 -- Prescription vial barcode or RFID tagged.

Referring to Figure 7, the pill vial for prescription drugs is available in numerous sizes. This figure is intended to depict where the RFID tag might be affixed to the vial. In most instances the prescription or RX label is affixed to the vial body and contains the barcode if used in lieu of RFID tag. This figure as stated depicts a prescription drug vial. However, the RFID tag and prescription (RX) label with barcode could also be affixed to liquid containing bottles and squeezable toothpaste-like tubes.

Statistics for costs of long term care and age projections in Illinois are similar to the national figures. Those statistics may be summarized as follows.

Illinois Long-Term Care Facts

1997 United States Census Bureau Statistics

Long-Term care facts:

5 Almost half of Illinoisans aged 65 or older will eventually need long-term care. Such care could include in-home help with the activities of daily living, such as dressing or bathing, or it could include skilled medical attention given in a nursing home.

10 Illinois' average cost of one year of long-term care is \$13,000 for in-home services and \$36,500 for a nursing home, with inflation adding another 6% per year.

Projected Distribution of the Elderly Population by Age

Percent of Elderly Population

	Age Group	1985	2010	2035	2050
15	65 to 69	32.2	29.9	24.0	24.6
	70 to 74	26.6	21.8	24.3	20.0
	75 to 79	19.6	17.4	21.0	17.1
	80 to 84	12.2	14.0	14.8	14.6
20	85 to Over	09.4	16.9	16.0	23.7

25 A large multi-employer pension fund recently reported that their retirees for the first time ever, out number the active participants. This trend will continue to be seen in other pension funds in the future.

30 Using state of Illinois facts, United States Census Bureau statistics and recent newspaper articles, the need for an Interactive Prescription Compliance and Life Safety Monitoring System is dramatically illustrated. The aging of Americans is accelerating at an alarming rate. Also accelerating at alarming rates are Medicare and Medicaid fraud and elderly care costs. These articles and statistics support the need for my patent application.

35 This application -- taken as a whole with the specification, claims, abstract, and drawings -- provides sufficient information for a person having ordinary skill in the art to practice the invention disclosed and claimed herein. Any measures necessary to

practice this invention are well within the skill of a person having ordinary skill in this art after that person has made a careful study of this disclosure.

Because of this disclosure and solely because of this disclosure, modification of this method and apparatus can become clear to a person having ordinary skill in this particular art. Such modifications are clearly covered by this disclosure.

What is claimed and sought to be protected by
10 Letters Patent is:

25
C L A I M S

1. An interactive personal safety system for a person comprising:

(a) an outward communication means being connected to a customer service center;

5 (b) a personal activating means connected to the outward communication means;

(c) an automatic activating means connected to the outward communication means;

10 (d) a programmable timing mechanism interconnecting the outward communication means, the personal activating means, the automatic activating means and the customer service center;

(e) the programmable timing mechanism being adapted to connect the automatic activating means to customer service center, when the personal activating means fails to activate for at least one preset time;

15 (f) a return communicating means connecting the customer service center to the outward communication means;

20 (g) a response means being connected to the customer service center; and

25 (h) the response means activating a team indicator so that the return communication means can require an appropriate assistance team upon failure to respond to a notice from the return communication means.

2. The interactive personal safety system of Claim 1 further comprising:

5 (a) the personal activating means being at one least one selected from the group consisting of a telephone, a home sensing device, at least one bar code, and at least one radio frequency identification tag; and

(b) the response means being connected to the team and the return communication means through the customer service center.

3. The interactive personal safety system of Claim 2 further comprising:

(a) the at least one bar code and the at least one radio frequency identification tag providing at least one identification mechanism;

(b) the at least one identification mechanism being applied to a functional member selected from the group consisting of at least one caregiver and at least one medicine; and

(c) the programmable timing mechanism being activatable by the at least one identification mechanism.

4. The interactive personal safety system of Claim 3 further comprising:

(a) the programmable timing mechanism requiring activation for at least one predetermined time by the at least one identification mechanism; and

(b) the automatic activating means being triggered upon failure to meet the at least one predetermined time.

5. The interactive personal safety system of Claim 4 further comprising:

(a) the programmable timing mechanism including at least one set off alarm mechanism selected form the group consisting of a fire alarm, a burglar alarm, a water alarm, a temperature alarm, an electricity alarm, a carbon monoxide alarm, a panic button alarm, a perimeter monitoring alarm, a keyless entry systems, an interactive video alarm, and an interactive audio alarm;

(b) the programmable timing mechanism including at one human code selected from the group consisting of a nurse code, a meal server code, and a therapist code; and

(c) the programmable timing mechanism including at one medical code selected from the group consisting of an electrocardiogram, a renal monitor, and an oxygen monitor.

6. The interactive personal safety system of
Claim 5 further comprising:

(a) the interactive video providing monitoring for
an individual patient;

5 (b) the interactive audio providing monitoring for
an individual patient;

10 (c) the customer service center including a
database storage of information relating to compliance
based on data from the personal activating means and the
automatic activating means; and

(d) a recovery means for recovering data from the
data base storage.

7. The interactive personal safety system of
Claim 6 further comprising:

(a) the outward communication means including a
set top box;

5 (b) the set top box having a communication link
with the customer service center;

(c) the set top box including an electronics
microprocessor to processes data received from the
customer service center; and

10 (d) a medicine supply being activatable through
the set top in order to dispense at least one medicine
from the medicine supply at least one desired interval.

8. The interactive personal safety system of
Claim 7 further comprising:

(a) the return communication means including a
television activating means cooperating with the set top
5 box; and

(b) the set top box including at least one feature
selected from the group consisting of a computer
processing unit, a solid state memory support, a radio
frequency receiver, at least one connecting port, a user
10 interface having at least one alarm button and at least
one reset button, a display device, a video overlay
circuit, an audio alarm; a visual alarm, bar code, a
radio frequency identification tag reader, a radio
frequency identification tag scanner, a drug dispenser
15 port, a modem, an ethernet 10 base t converter, a wide
area network converter, an auto dialer, a back-up power
source, and a priority interrupting system.

9. The interactive personal safety system of
Claim 8 further comprising:

(a) the set top box including at least one item
selected from the group consisting of a wireless safety
5 device, a security device, a display pager, a cellular
telephone, and a wireless telephone; and

(b) the set top box being connected to at least
function selected from the group consisting of a drug
dispenser, an interactive audio medical monitor, and an
10 interactive video medical monitor.

10. The interactive personal safety system of
Claim 9 further comprising:

5 (a) the interactive audio medical monitor and the
interactive video medical monitor being at least
selected from the group consisting of an electro
cardiogram, a renal function monitor, an oxygen monitor
and a blood pressure monitor; and

10 (b) the wireless safety device and the security
device being at least selected from the consisting of a
fire alarm, a burglar alarm, a motion detector, a
temperature sensor, a carbon monoxide detector, a water
sensor, an electricity sensor, a wrist mounted panic
button, a pendant panic button, a perimeter limiting
alarm, a video camera and a keyless door entry.

11. The interactive personal safety system of
Claim 10 further comprising:

5 (a) the bar code serving to correctly identify a
user or a medicine; and

(b) the radio frequency identification tag serving
to identify the user and the medicine.

12. The interactive personal safety system of
Claim 11 further comprising:

5 (a) the bar code and the radio frequency
identification tag providing log-in and log-out entries
for at least one service provider and alerting the
customer service center of the dates and times service
and goods were provided to user; and

10 (b) a failure to log-in or log-out causing an
alarm condition at the customer service center and
follow-up notification.

13. The interactive personal safety system of
Claim 12 further comprising:

5 (a) the alarm condition including a delay in order
avoid unnecessary action; and

(b) the alarm condition including at least one
audio warning.

14. The interactive personal safety system of
Claim 13 further comprising:

- (a) a billing function being connected therewith;
- (b) a personal identification number being placed
in the set top box;
- (c) an adjustable service level being provided to
the set top box; and
- (d) a testing mechanism for the interactive
personal safety system.

15. An interactive prescription compliance and
personal safety system, requiring both a user of the
system to respond to alarm signals generated by a
customer service center, and the customer service center
to respond to alarm signals generated by the user, the
interactive system comprising:

- A. a pharmacy data terminal being adapted to
record personal and prescription information
of the user;
- B. a reader for a coding means on a prescription
dispenser identifying at least one
prescription taken by the user, the coding
means being at least one selected from the
group consisting of a bar code and a radio
frequency identification tag;
- C. the customer service center communicating with
the pharmacy data terminal, the reader, and
the user in order to create a permanent
patient data base;
- D. the customer service center providing
electronic data storage and prescription
information for the user and communicating
with a data processing center, in order to
provide prescription information;
- E. the customer service center being connected to
a prescription compliance alarm;
- F. the prescription compliance alarm being
connected to a dispenser for medication;
- G. the reader including an activation means for

the prescription compliance alarm adapted to signal use or non use of the dispenser and to cause a response to non use;

5 H. the activation means including at least one selected from the group consisting of a console receiving and displaying a prescription compliance messages and an audio alarm;

10 I. the reader being adapted to read the coding means and being connected to the activation means; and

J. the reader serving to deactivate the alarm when a proper medication code is provided.

16. The interactive prescription compliance and personal safety system of Claim 15 further comprising:

5 A. the reader providing a display means, the display means being selected from the group consisting of liquid crystal display and a television screen;

B. the reader including an activating means for sounding an audio alarm;

C. the audio alarm providing an indication of when to take medication;

D. the audio alarm cooperating with the reader in order to provide an indication of whether medication is proper; and

E. the reader informing the data processing center of compliance or non compliance.

15 17. The interactive prescription compliance and personal safety system of Claim 16 further comprising:

A. the reader receiving information of medication by the user from the coding means;

B. the reader generating a signal; and

C. the reader sending the signal to the data processing center in order to verify medication being taken.

18. The interactive prescription compliance and personal safety system of Claim 17 further comprising:

- A. the reader receiving information of at least one service provider;
- B. the data processing center using conventional communications links, accepting all required data for the user, and, creating a permanent patient data base;
- C. the data processing center having prescription information of least one selected from the group consisting of dosage, time interval, and level of service options and accessories is stored;
- D. the data processing center generating a prescription compliance alarm in order for the user to cause medication to be dispensed; and
- E. the data processing center generating a non-compliance alarm after a personal safety alarm is detected.

19. A method of providing interactive prescription compliance and life safety alarms for a user, the method comprising:

- A. providing a patient prescription record for at least one medication and life safety profile in a database;
- B. generating prescription compliance alarm from the profile and the database;
- C. downloading the database through the compliance alarm to require the user to remove medication from a dispenser;
- D. causing the user to pass the medication in front of reader;
- E. generating a compliance signal to the data base in order to verify medication removal from the dispenser in order to indicate compliance; and
- F. recording the compliance in the database.

5

20. The method of Claim 19 further comprising:

- A. generating a life safety alarm signal;
- B. transmitting the life safety alarm signal to the database thereby recording date, time, and nature of the safety alarm signal;
- C. relaying the life safety alarm to a correct authority;
- D. monitoring a service provider, an equipment provider and medical life support equipment;
- E. providing an interactive audio and video system in a home of the user;
- F. controlling the interactive audio and video system in a home of the user through a designated third party; and
- 10 G. utilizing a home telephone number and assigning that number to a pager-like device in order to provide compliance alarms, which is stored and activated at appropriate medication times.

15

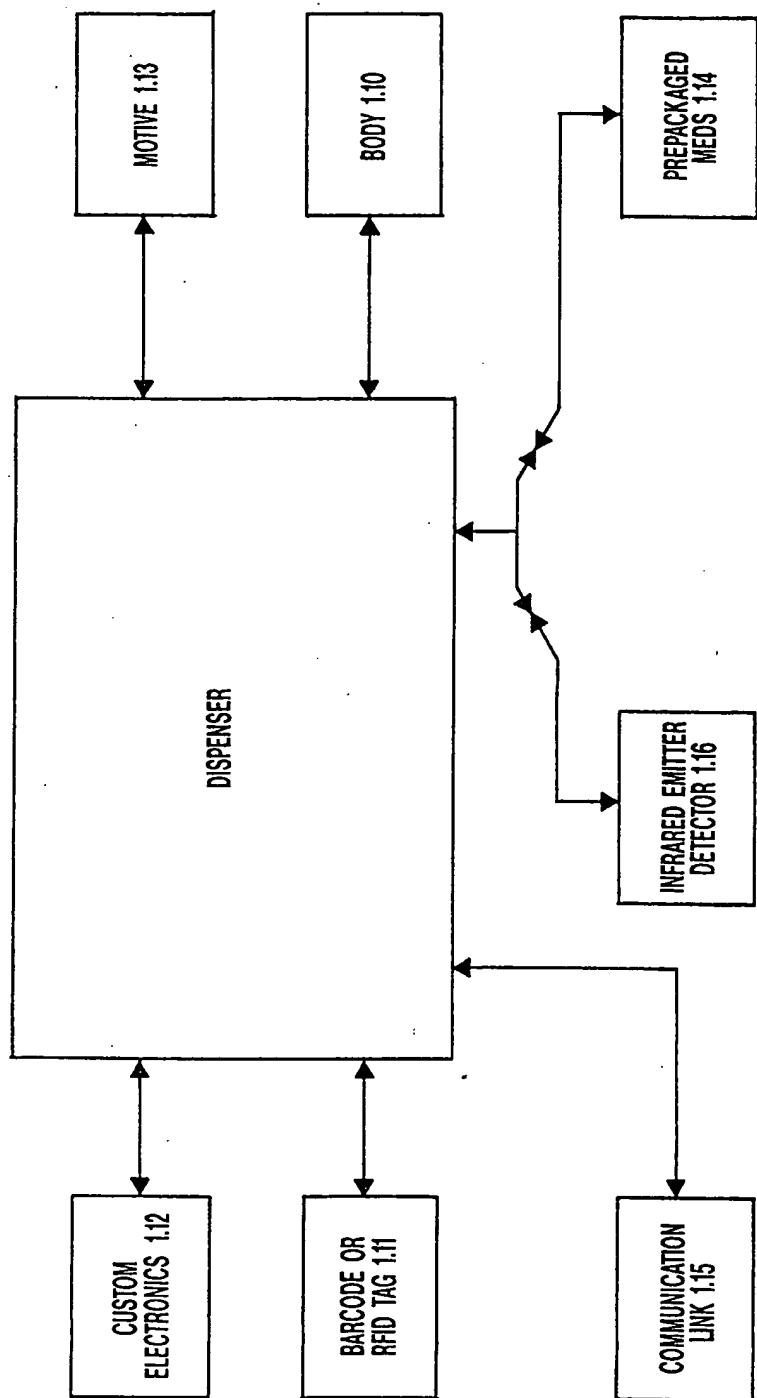


Fig.1.

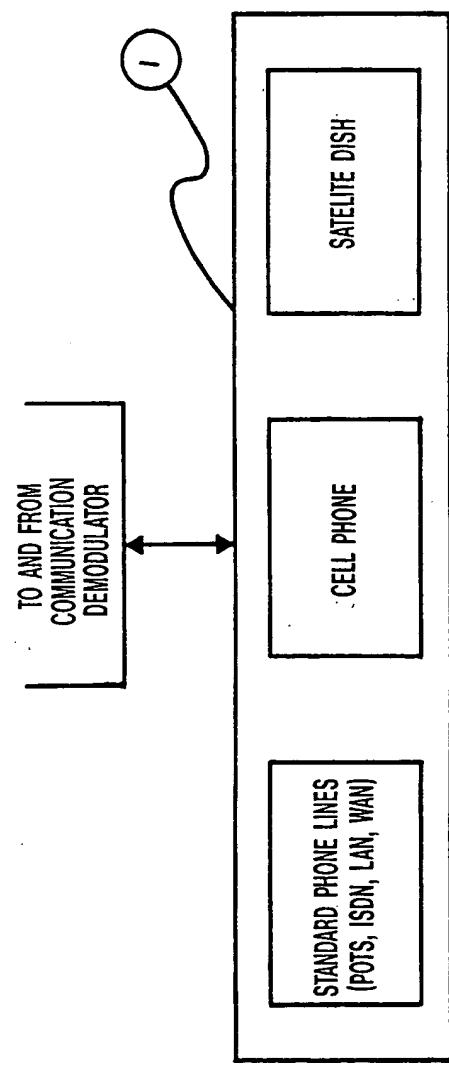


Fig.2.

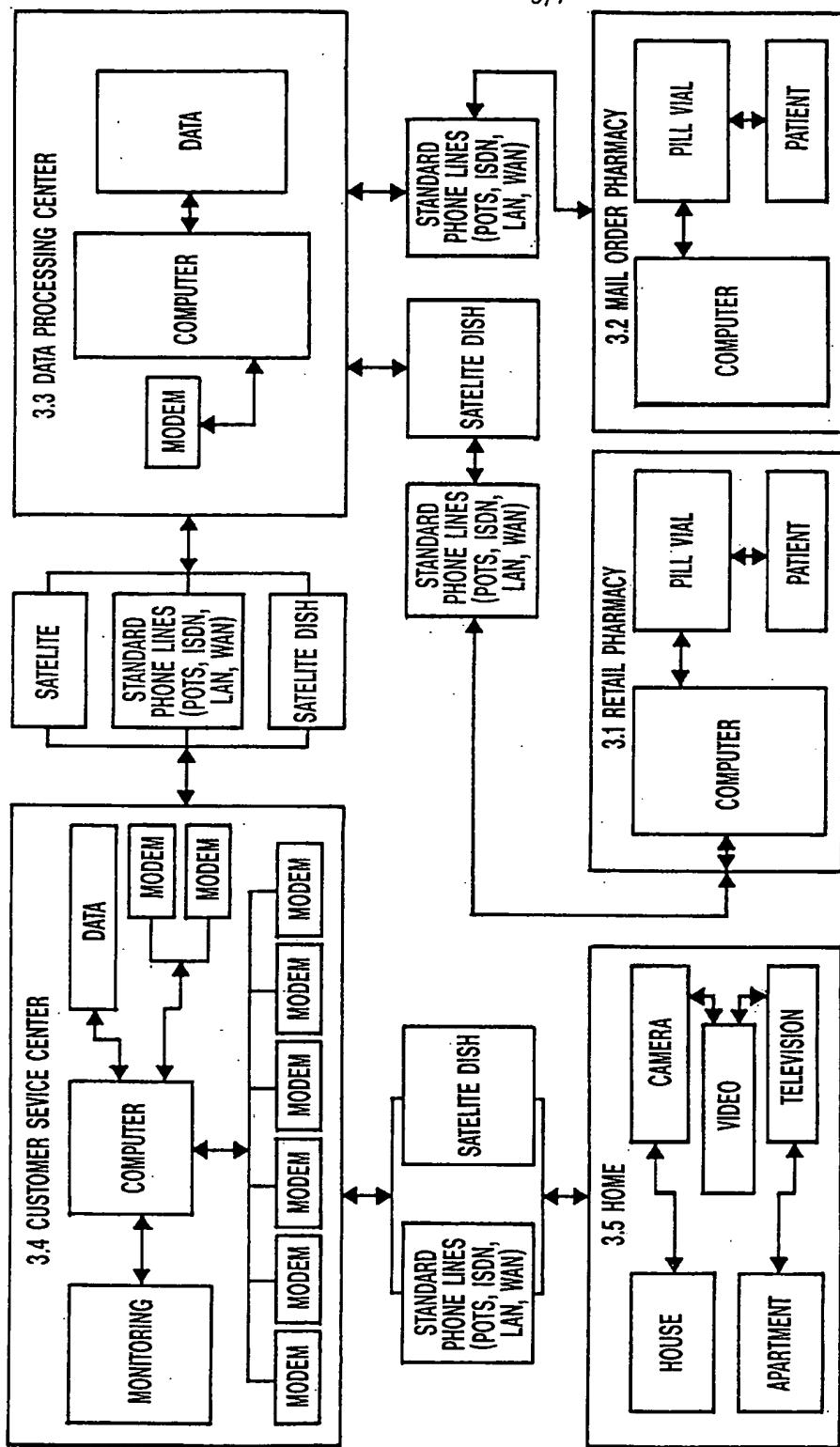


Fig. 3.

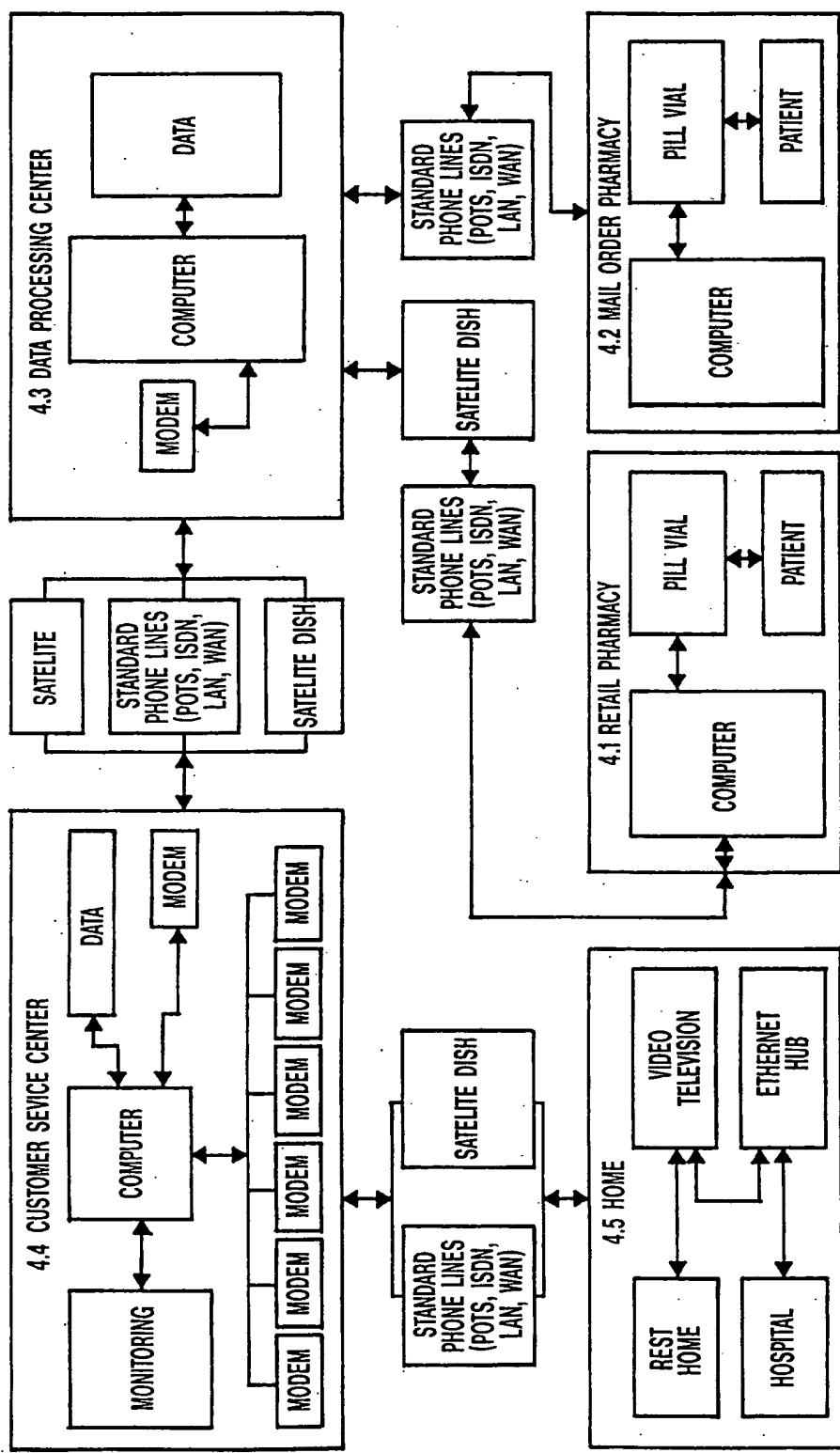


Fig.4.

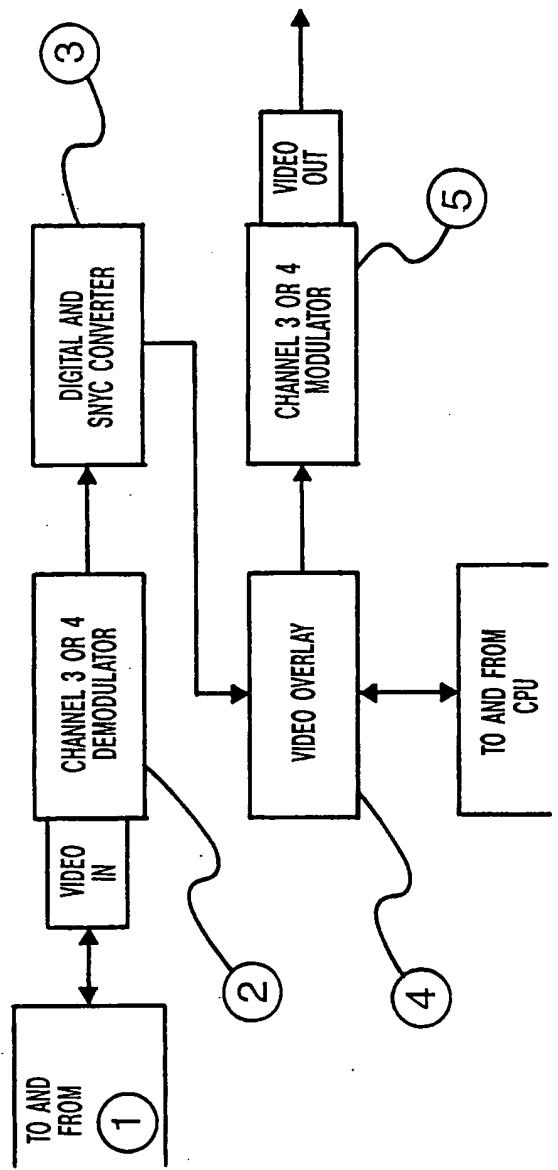


Fig. 5.

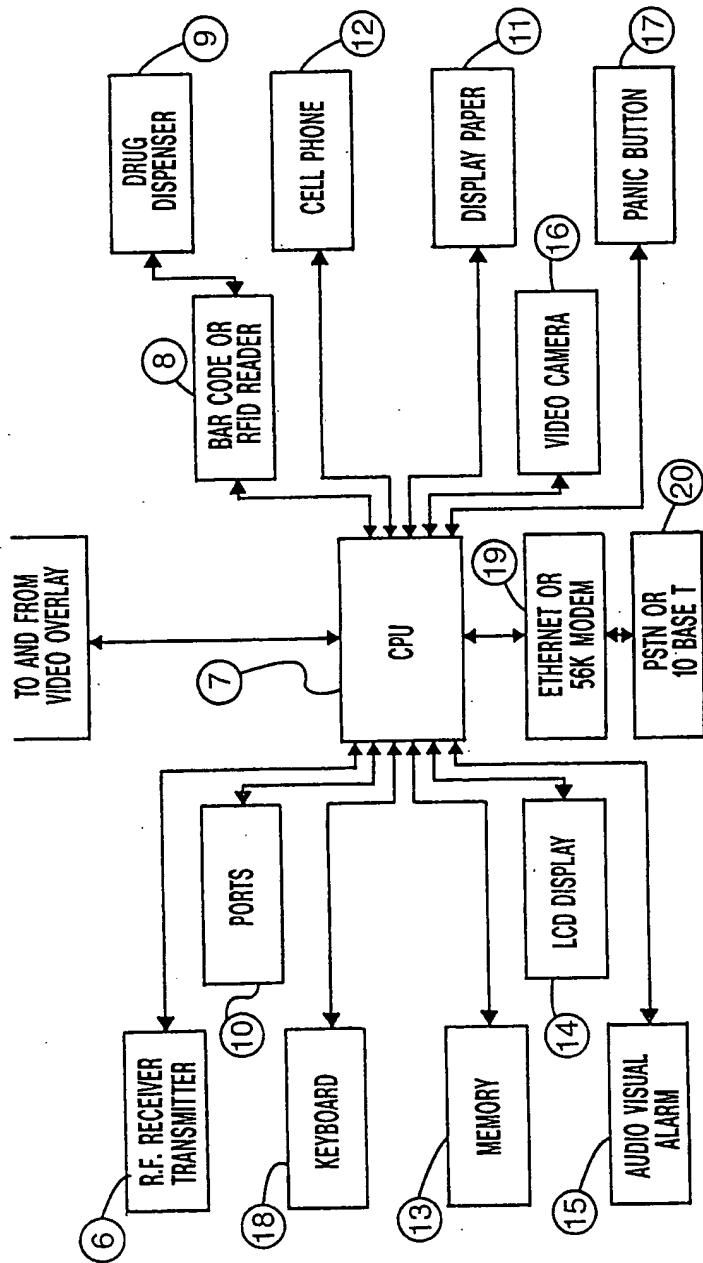


Fig.6.

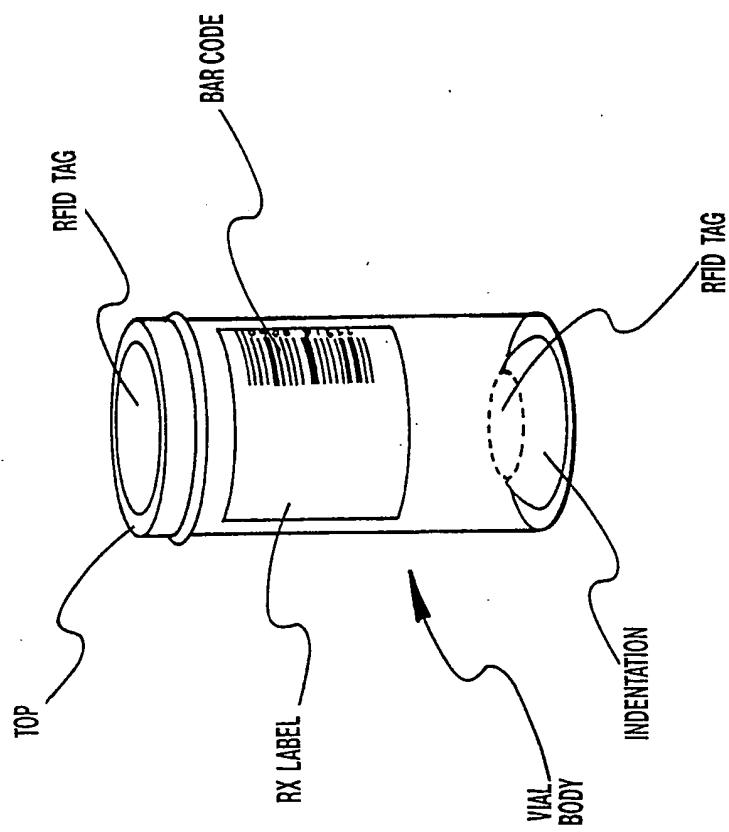


Fig. 7.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/15612

A. CLASSIFICATION OF SUBJECT MATTER																				
IPC(6) :G08B 21/00 US CL :340/573.1, 825.36; 364/400; 379/38 According to International Patent Classification (IPC) or to both national classification and IPC																				
B. FIELDS SEARCHED																				
Minimum documentation searched (classification system followed by classification symbols) U.S. : 340/573.1, 825.36; 364/400; 379/38																				
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched NONE																				
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) NONE																				
C. DOCUMENTS CONSIDERED TO BE RELEVANT																				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																		
A	US 5,512,935 A (MAJETI ET AL.) 30 April 1996 (30/04/96), see the Abstract and figure 1.	1-20																		
A	US 5,623,242 A (DAWSON, JR. ET AL.) 22 April 1997 (22/04/97), see entire document, especially figure 1.	1-20																		
A, P	US 5,852,408 A (CHRISTIANSEN ET AL.) 22 December 1998 (22/12/98), see the Abstract.	1-20																		
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.																				
<table> <tr> <td>* Special categories of cited documents:</td> <td>*T*</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>*A*</td> <td>document defining the general state of the art which is not considered to be of particular relevance</td> <td></td> </tr> <tr> <td>*B*</td> <td>earlier document published on or after the international filing date</td> <td>*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>*L*</td> <td>document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>*O*</td> <td>document referring to an oral disclosure, use, exhibition or other means</td> <td></td> </tr> <tr> <td>*P*</td> <td>document published prior to the international filing date but later than the priority date claimed</td> <td>*&* document member of the same patent family</td> </tr> </table>			* Special categories of cited documents:	*T*	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	*A*	document defining the general state of the art which is not considered to be of particular relevance		*B*	earlier document published on or after the international filing date	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	*L*	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	*O*	document referring to an oral disclosure, use, exhibition or other means		*P*	document published prior to the international filing date but later than the priority date claimed	*&* document member of the same patent family
* Special categories of cited documents:	*T*	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention																		
A	document defining the general state of the art which is not considered to be of particular relevance																			
B	earlier document published on or after the international filing date	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone																		
L	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art																		
O	document referring to an oral disclosure, use, exhibition or other means																			
P	document published prior to the international filing date but later than the priority date claimed	*&* document member of the same patent family																		
Date of the actual completion of the international search 16 AUGUST 1999	Date of mailing of the international search report 21 OCT 1999																			
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer GLEN R. SWANN, III Telephone No. (703) 305-4384																			

Joni Hill